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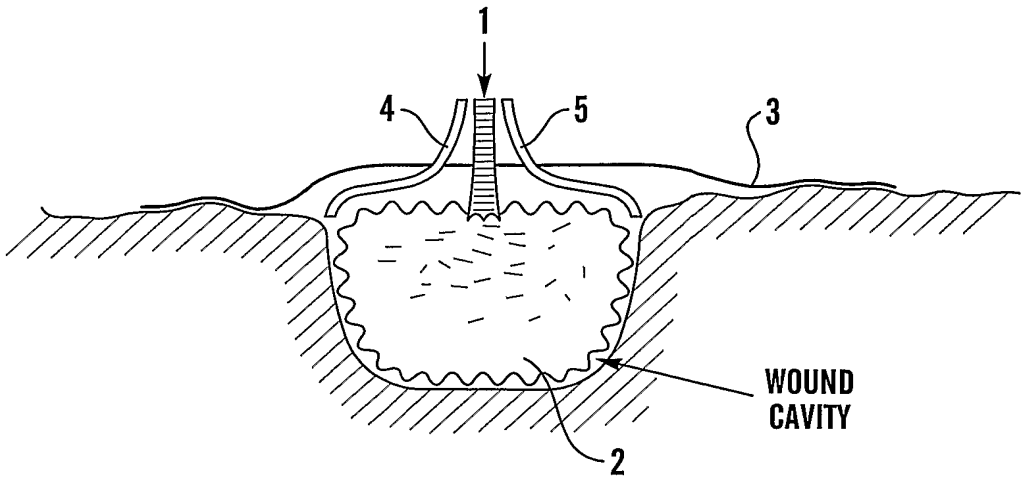
(54) Title: TISSUE TREATMENT DEVICE



(57) Abstract: The tissue treatment device consists of a bladder (2), having inlet (1) to be connected to a fluid source (not shown). The bladder (2) is placed within a wound cavity and inflated to conform to the cavity shape and apply constant pressure against the wound surface or pulsed pressure, as required. A seal (3) isolates bladder (2) and the wound cavity from atmosphere. Seal (3) includes one or more inlets/outlets (4, 5) for connection to a vacuum source and/or for the supply of media to be introduced into the wound cavity. The vacuum source can be a vacuum pump or a continuous vacuum provided in hospitals. The media to be introduced into the wound cavity can be saline, water or ozone, oxygen, or any substance to promote wound healing. The bladder (2) is made from polymeric material and can also be impregnated with wound healing compounds to promote healing.

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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

Tissue Treatment Device

This invention relates to a wound healing device, in particular a device using vacuum or suction therapy for enhanced drainage of the wound to promote wound healing.

With the ageing of the world's population the clinical and cost impact of several categories of soft tissue wounds is increasing including pressure ulcers, vascular ulcers and diabetic foot ulcers. Not only is it required to accelerate healing of such wounds compared with conventional methods but also to succeed in healing the minority which are impossible to heal with conventional methods.

A solution to this problem not only reduces suffering by patients but also the considerable cost of conventional wound care products and the associated healthcare labour.

It has been known since the 1980s that the application of a vacuum to a wound by its suction action provides an antiseptic effect, promotes wound clearing from bacteria, pus and necrotic masses and promotes quicker filling of the wound with granulation tissues, thereby providing a faster rate of healing.

Prior art vacuum systems comprise a cover to seal the wound and a vacuum applied to the wound surface. Typically, the vacuum is applied to the wound surface by means of a suction pump with drainage tube within a porous dressing provided under the cover for the wound space so that exudates are siphoned from the wound. Alternatively, the suction pump with drainage tube or tubes is attached to a flexible pouch which is either porous or with holes on its surface so that exudates are drawn from the wound space into the pouch to be carried away from the wound.

The present invention aims to make improvements. Accordingly, the present invention provides a device for treatment of a wound comprising an inflatable bladder to be placed over a wound, the bladder inflated to conform to the wound surface, sealing means to isolate the bladder and the wound surface from the atmosphere and vacuum means to apply a vacuum to the area between the bladder and the wound and drain exudates from the wound. The bladder is inflated to take up the area within the wound cavity that is normally filled with a packing material such as sponge or similar. Such packing material has its problems of retaining wound exudate within it, becoming enmeshed with the tissue within the wound and tearing the tissue ingrained upon removal of the dressing. Also, the bladder is not used to convey the exudates from the wound as with prior art devices and advantageously continues to apply an even pressure against the wound cavity surface which is comfortable even when the body rests against the device.

In a preferred embodiment, the inflated bladder applies an alternating pressure against the wound cavity surface, to induce perfusion of the wound surface for quicker healing. Preferably, the bladder comprises a surface area of greater magnitude to that of a wound cavity within which it is to be used in order to provide folds of the bladder against the wound cavity surface when inflated. The folds provide areas between the bladder and the wound surface for suction. Preferably, the bladder comprises convolutions within its outer surface or more preferably, an uneven surface texture.

More preferably, the bladder is in the form of a bellows, the number used depending on the size of the wound cavity.

Moreover, the bladder comprises two layers, an inner layer and an outer layer, the outer layer being convoluted and having an inlet and a plurality of apertures to introduce media into the wound cavity. In this way, ozone or a similar bacterial growth inhibitor can be introduced to the wound cavity. Alternatively, oxygen could be introduced into the wound cavity for local oxygenation. Similarly, saline solution or liquid disinfectant could be introduced to the wound cavity to inhibit infection. Preferably, the media introduced into the wound cavity is heated to provide normothermic wound surface heating. Alternatively, for a simpler construction, the bladder preferably is of gas permeable material, the fluid inflating the bladder, say for example ozone or oxygen, allowed to permeate into the wound cavity.

Preferably, the bladder is transparent or translucent to allow for visual inspection of the wound without the need for removal of the device. As an additional means of promoting the healing of the wound, the bladder includes light emitting means, for example laser or polychromatic light, or more preferably, electrical stimulation means to stimulate the wound cavity surface.

The invention will be now be further described by way of example, with reference to the accompanying drawings, in which:

Figure 1 shows a cross sectional view of one embodiment of a device according to the invention;

Figure 2 shows the device in Figure 1 where the inlets to the bladder and vacuum means are coaxially located;

Figure 3 shows another embodiment of a device providing heating; and

Figures 4 to 6 show alternative versions of the bladder for the device.

Referring to Figure 1, the device consists of a bladder 2, having inlet 1 connected to a fluid source (not shown). The bladder 2 can be of any suitable polymeric material, for example polyurethane, PVC or polyethylene and can also be impregnated with wound healing compounds to promote healing. The bladder 2 is inflated by means of inlet 1 and placed within a wound cavity to generally conform to the cavity shape. A one way valve (not shown) at the inlet 1 maintains the bladder 2 in its inflated state. The bladder 2 can be inflated by any suitable means for example, a hand pump or a compressor. The bladder 2 can be inflated to provide constant pressure against the wound surface or alternatively, with some modifications known in the art can be inflated alternately to provide pulsed pressure. A seal 3, which can be any adhesive film or flexible polymer sheet with adhesive applied to the surface facing the tissue seals the bladder 2 and the wound cavity from atmosphere. The seal 3 overlies the bladder 2 and extends beyond the wound area onto intact tissue. The seal 3 includes one or more inlets/outlets 4, 5 for connection to a vacuum source and/or for the supply of media to be introduced into the wound cavity. The vacuum source can be a vacuum pump or a continuous vacuum provided in hospitals. The media to be introduced into the wound cavity can be saline, water or ozone, oxygen, or any substance promoting wound healing.

In one embodiment, the seal 3 is provided with one tube 4 connected to a vacuum source and supply of media with suitable controls to operate the vacuum and supply as required. Alternatively, the seal 3 can be provided with a plurality of tubes 4, 5 to provide a vacuum 4 and

supply of media 5 separately. These two in combination provide a controlled rate of flow of media across the wound surface at a pressure substantially below atmospheric pressure with any wound exudate scavenged along to the vacuum exit tube 4. The tubes 4, 5 can be located coaxially or concentrically in one location on the seal 3 (see Figure 2) or located in any desired position on the seal 3. The seal 3 can also be provided with a collar 19 to support the tubes 4, 5.

The bladder 2 can simply be evacuated and made smaller when it has to be removed from the wound cavity without causing any damage to the wound surface. Furthermore, during healing of the wound, as the wound cavity shrinks so can the bladder by removal of the inflation fluid. Therefore there is no requirement for changing the wound healing device.

In another preferred embodiment, the bladder inlet and vacuum inlet are operated by the same pump, the pump inflating the bladder insitu within the wound cavity and then switching over to apply a vacuum to the wound cavity. Furthermore, the vacuum can be applied to the bladder to facilitate removal of the bladder from the wound cavity.

As shown in Figure 3, the bladder 2 is provided with an inlet 1 and an outlet 7 connected to a compressor 8 and heater 9. Thus, the bladder 2 is inflated with heated air to provide heating to the wound surface, the heating promoting perfusion of the area. The air can be replaced by water to provide the same effect.

The bladder 2 can be of transparent or translucent material to allow visual inspection of the wound surface without having to remove the seal. The translucent bladder 2 can also be provided with optical fibres to provide light to the wound surface to stimulate healing.

These optical fibres can run co-axially down the inlet 1 tube and terminate at entry to the bladder 2, permitting illumination of the wound cavity. In another embodiment, the walls of the inlet 1 tube itself may act as a light conduit from a light source in the fluid pump, and light evenly dispersed around the wound cavity by the bladder 2 material acting as a diffuser. This is an improvement over current phototherapy treatment methods, where illumination is only possible during change of dressing. With the method described above, illumination can occur continuously if necessary, either at 100% power level or pulsated, and at different wavelengths, under the control of a computer system inside the fluid pump.

Similarly, the wound surface can be subjected to magnetic pulse therapy by using intermittent alternating voltage applied as a coil. Typically, a coil is placed within a sealed cover and manipulated so that the coil axis is at 90° to the wound surface, when energised the coil ensures that the wound surface is placed at an alternating magnetic field of sufficient intensity to promote wound healing.

The bladder 2 can also be impregnated with interdigitated electrodes for direct electrical wound surface stimulation, known to promote healing, or the bladder can be of a conductive material connected electrically.

The wound healing device of the present invention can be used on a range of wounds, the bladders taking any shapes and sizes to accommodate differing wound cavities from shallow to irregular and deep wounds. Figures 4 to 6 show some variations of the bladder configurations but any size or shape is possible. Figure 4 shows the bladder 2 within a shallow wound cavity. Figure 5 shows the bladder as a series of bellows, the number depending upon

the wound size. Figure 6 shows the bladder having an inner layer and an outer layer.

CLAIMS

1. A device for treatment of a wound comprises an inflatable bladder to be placed over a wound, the bladder inflated to conform to the wound surface and maintained in the inflated state, sealing means to isolate the bladder and the wound surface from the atmosphere and vacuum means to apply a vacuum to the area between the bladder and the wound and drain exudates from the area.

2. A device as claimed in claim 1 wherein the bladder surface has folds resting against the wound cavity surface, when inflated.

3. A device as claimed in claims 1 or 2 wherein the bladder outer surface comprises convolutions.

4. A device as claimed in claims 1, 2 or 3 wherein the bladder outer surface has an uneven texture.

5. A device as claimed in claim 1 wherein the bladder is in the form of a bellows.

6. A device as claimed in claims 1, 3 or 4 wherein the bladder comprises an inlet and a plurality of apertures to introduce media into the wound cavity by means of the inlet.

7. A device as claimed in claim 6 wherein the media introduced into the wound cavity is heated to provide normothermic wound surface heating.

8. A device as claimed in claims 1 to 5 wherein the bladder is of gas permeable material, the fluid inflating the bladder allowed to permeate into the wound cavity.

9. A device as claimed in any preceding claim wherein the bladder is transparent to allow for visual inspection of the wound.

10. A device as claimed in any preceding claim wherein the bladder includes light emitting means to stimulate the wound surface.

11. A device as claimed in any preceding claim wherein the bladder includes electrical means to stimulate the wound surface.

12. A device as claimed in any preceding claim wherein the bladder is inflated by alternating pressure.

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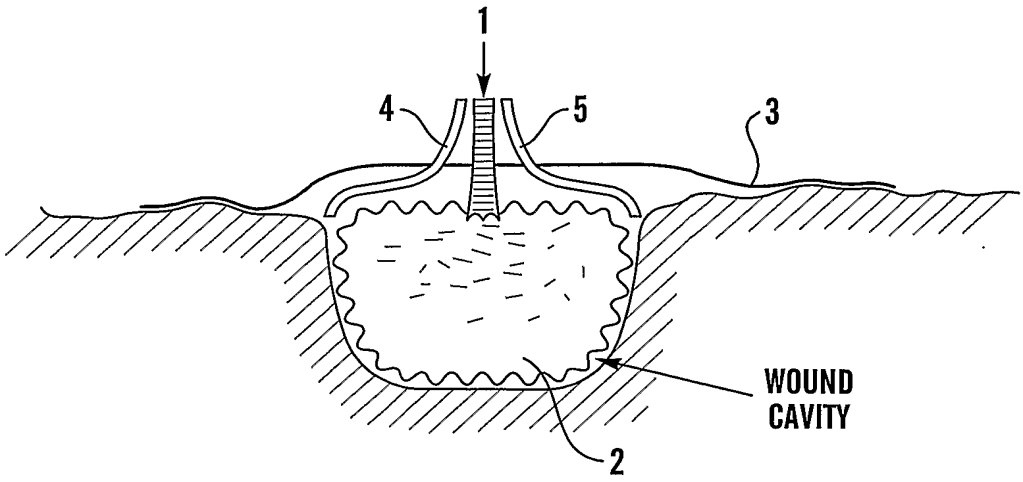

Fig.1

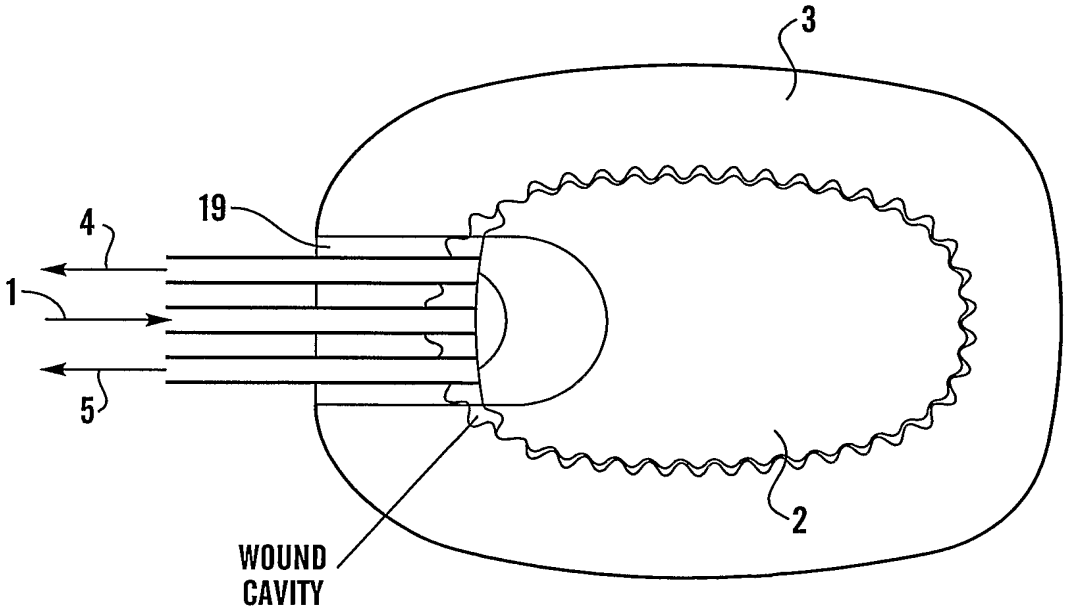

Fig.2

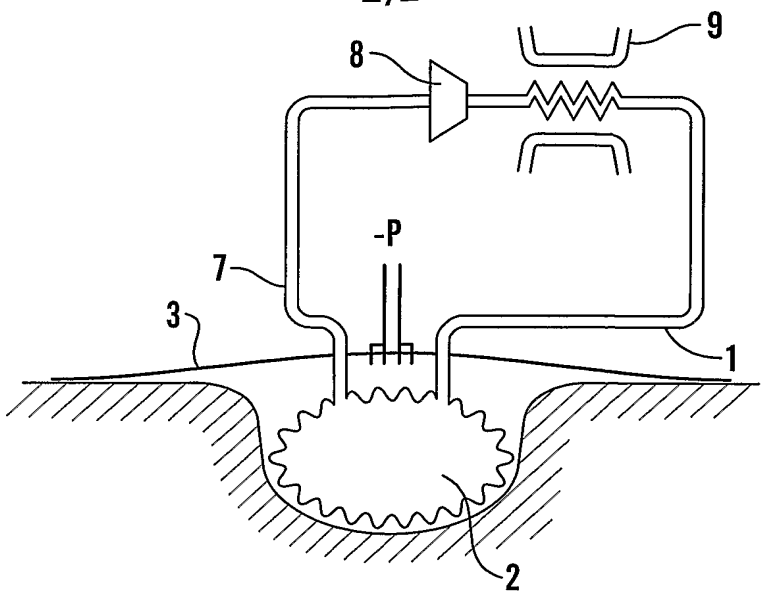

Fig.3

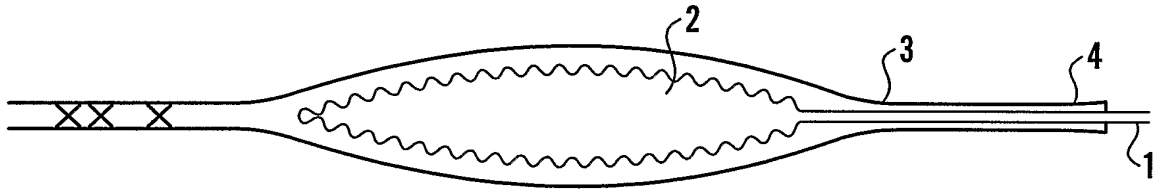

Fig.4

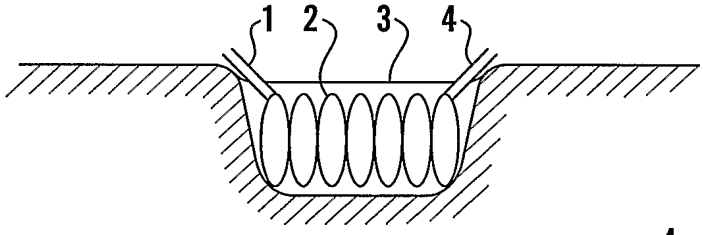

Fig.5

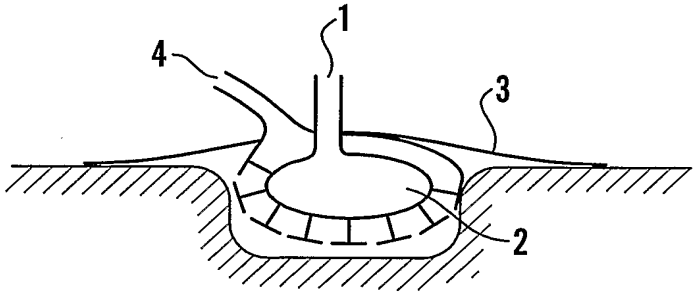

Fig.6

INTERNATIONAL SEARCH REPORT

Inte ial Application No
PCT/GB2005/000679

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M1/00 A61M27/00 A61F7/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	GB 2 378 392 A (* RECUPERATIO LIMITED) 12 February 2003 (2003-02-12) page 8, paragraph 3 - page 9, paragraph 3; figure 7 page 5, paragraph 2 - page 7, paragraph 3; figures 1-4	1-4,6,7, 9
X	WO 03/070135 A (TWO BEATS; STALDER, ALBERT, GEORGE; STALDER, MINDY, LAREINE, AMELN) 28 August 2003 (2003-08-28) page 7, line 30 - page 9, line 10 page 10, line 25 - page 11, line 4 figures 1-3,7	1-7,9

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
6 June 2005	22/06/2005

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Lakkis, A

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INTERNATIONAL SEARCH REPORT

Int...al Application No
PCT/GB2005/000679

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P,X	WO 2004/037334 A (SMITH & NEPHEW PLC; BLOTT, PATRICK, LEWIS; GREENER, BRYAN; HARTWELL, E) 6 May 2004 (2004-05-06) page 50, line 22 - line 24 page 62, line 31 - page 64, line 29; figures 13a,15,16a page 67, line 21 - line 23	1

Form PCT/ISA/210 (continuation of second sheet) (January 2004)

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/GB2005/000679

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WO 03070135	A	28-08-2003	NL	1020049 C2	25-08-2003
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